



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,905	02/23/2004	Charles Ebert	22868.NP	6139
28122	7590	06/20/2007	EXAMINER	
THORPE NORTH & WESTERN P.O. BOX 1219 SANDY, UT 84091-1219				COTTON, ABIGAIL MANDA
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
06/20/2007		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/784,905	EBERT, CHARLES
	<b>Examiner</b>	<b>Art Unit</b>
	Abigail M. Cotton	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 2/23/04, 6/28/04, 7/10/04, 12/27/04, 1/18/05.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-24 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a testosterone oral dosage formulation comprising a solid polyethylene glycol carrier and testosterone, classified in class 424, subclass 435, for example.
- II. Claims 11-14, drawn to a method of administering testosterone or treating or ameliorating a condition for which testosterone is effective by orally administering a testosterone formulation, classified in class 424, subclass 435, for example.
- III. Claims 15-24, drawn to a method of making an oral dosage testosterone formulation by forming a dispersion of testosterone in a molten polyethylene glycol carrier, cooling the dispersion and dividing the mass into portions suitable for administration, classified in class 424, subclass 435, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product. See MPEP § 806.05(h). In the instant case, the process for using the product can be practiced with a materially different product, such as an oral dosage form having testosterone in a carrier other than polyethylene glycol.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I and II may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group I, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Group II. Conversely, in searching Group II, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product could be made by a materially different process, such as by incorporating different heating or cooling steps, or by encapsulating the testosterone within a polyethylene glycol casing.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I and III may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group III, the Examiner will be focusing on the patentability of the process itself, and not the composition of Group I. Conversely, in searching Group I, the Examiner will be focusing on the patentability of the composition and not the process itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because Group II is directed to utilizing a composition comprising testosterone, whereas Group III is directed to a method of preparing the composition. Thus, the methods have different functions and effects. The inventions are also not disclosed as capable of use together, because the steps involved in the process of making and the process of using the composition are temporally separated. That is, the steps of using the composition for administering testosterone or treating conditions are not taught as being equivalent to, or useful as, steps performed for the purpose of preparing the composition, and vice versa.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups II and III may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group II, the Examiner will be focusing on the patentability of the process of utilizing itself, and not the process of preparing of Group III. Conversely, in searching Group III, the Examiner will be focusing on the patentability of the process of preparing and not the process of utilizing the composition.

Accordingly, a search for both groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

Art Unit: 1617

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER